i. However, Defendants **actively concealed** and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a** Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiff. *See Investigative Report attached hereto as Exhibit "C."*

ii. Most egregiously, Defendants were issued another Form 483 when it **"erroneously used non-conforming material."** Defendants actively concealed this and was issued an additional Form 483 for "failing to adequately document the situation." Defendants actively concealed this from Plaintiff. *See Investigative Report attached hereto as Exhibit "C."*

iii. However, Defendants' facility was also issued a notice of violation as it **"no longer uses pre-sterile and post-sterile cages."** Defendants actively concealed this from Plaintiff. *See Notice of Violation attached as Exhibit "D."*

iv. However, Defendants also was issued a notice of violation when it **"failed to obtain a valid license...prior to manufacturing medical devices."** Defendants were manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiff. *See Notice of Violation attached as Exhibit "D."*

v. However, Defendants were also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. *See Notice of Violation attached as Exhibit "D."* Defendants actively concealed this from Plaintiff.

vi. Defendants failed to notice the FDA of their internal excel file containing **16,047 entries of complaints.**

vii. Yet, Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by Defendants** as "painful and is also known to be **highly inaccurate**, with false-positive results in as many as 40%."

viii. Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(b) "The Essure **inserts stay secure**, forming a long protective barrier against pregnancy. They also **remain visible outside your tubes**, so your doctor can confirm that they're properly in place."

i. However, the micro-inserts do not remain secure but migrate and are expelled by the body. Defendants actively concealed this information from Plaintiff.

ii. However, Defendants actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483 issued to Defendants by the FDA. *See Investigative Report attached hereto as Exhibit "C."*

iii. Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(c) "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. However, the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiff.

ii. PET fibers are not designed or manufactured for use in human implantation.

iii. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known."

iv. However, the PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion.

v. Most egregiously, Defendants were issued another Form 483 when it **"erroneously used non-conforming material."** Defendants actively concealed this and was issue another Form 483 for "failing to adequately document the situation." *See Investigative Report attached hereto as Exhibit "C."*

(d) "Surgery free"

i. However, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

(e) "Anesthesia-free"

i. However, Essure is not "anesthesia-free", rather anesthesia is not required.

(f) Step Two: "pregnancy **cannot** occur"; Step Three: The Confirmation.

i. However, Defendants also state that it is only **after** "The Confirmation" pregnancy cannot occur. i.e. the complete opposite of what is warranted in the brochure.

ii. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed.

iii. However, between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff.

iv. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

v. However, there have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[7].

(g) "Essure **eliminates** the risks, discomfort, and recovery time associated with surgical procedures."

i. However, Essure is not "surgery-free", rather surgery is not required.

ii. Yet, Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by Defendants** as "painful and is also known to be **highly inaccurate**, with false-positive results in as many as 40%."

116. The **PET fibers are what causes** the tissue growth.

(a) However, during the PMA meeting with the FDA, Defendants represented that the **trauma** caused by the expanding coil striking the fallopian tubes **is what caused the inflammatory response** of the tissue. Defendants concealed this information from Plaintiff.

(b) However, in the patent for Essure it states that a galvanic battery causes the tissue growth.

117. "The inserts are made from...**safe, trusted material**."

(a) However, the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, Defendants refer to Essure and classify it as a "drug."

[7] *Essure insert expulsion after 3-month hysterosalpingogram,*, US National Library of Medicine, Garcia, Al.

118. In January 2014, Defendants warranted that over 750,000 procedures had been performed.

(a) However, ten months later Defendants advised only 625,000 had been performed.

ESSURE BOOKLET WARRANTIES

119. Defendants' Essure booklet warrants:

(a) "This viewable portion of the micro-insert serves to verify placement and **does not irritate the lining of the uterus."**

i. However, the device does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendants concealed this information from Plaintiff.

i. However, Defendants actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483. *See Investigative Report attached hereto as Exhibit "C."*

i. Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(b) "there was no cutting, **no pain,** no scars…"

i. However, Plaintiff has experienced pain as a result of Essure. Defendants concealed this information from Plaintiff.

ii. Yet, Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by Defendants** as "painful and is also known to be **highly inaccurate,** with false-positive results in as many as 40%."

iii. Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for pain.

iv. However, Defendants altered the records of at least one trial participant to reflect less pain.

DATA WARRANTIES

120. Summary of Safety and Effectiveness Data states:

(a) "The Essure System provides permanent birth control without invasive surgery or general anesthesia, and their associated risks."

i. However, Essure is not "surgery-free" or "anesthesia-free", rather surgery and anesthesia is not required.

(b) "In addition to the above benefits, none of the women in the Essure clinical trials became pregnant while relying on Essure for contraception."

i. However, there were at least four pregnancies during the clinical trials. Defendants concealed this information from Plaintiff.

(c) "Namely, the Essure system is delivered hysteroscopically without general anesthesia."

i. However, Essure is not "surgery-free" or "anesthesia-free", rather surgery and anesthesia is not required.

PMA SUPPLEMENT

121. Defendants represented to Plaintiff that it was the expanding coil and tissue growth which caused the coil to be attached to the tube, not any type of coating.

(a) Yet, in Supplement 18, Defendants represented that "A doctor placed the coil at the uterine-fallopian tube junction, where **its coating caused it be attached** to the tube." The coating is a hydrophilic polymer coating produced by AST Products, Inc. Defendants actively concealed this from Plaintiff.

SEC FILINGS

122. Defendants warranted that the Essure system has **"no risks"** for patients because ... the Essure system does not involve the use of radiofrequency energy. *SEC Form 10-K filed on 3/15/11 by Defendants.*

(a) At the same time, Defendants also states that there are limited risks with Essure.

(b) At the same time, the patent for Essure alleges that the coils act as a galvanic battery.

123. "Our Mountain View, California facility underwent an International Organization for Standardization ("ISO") inspection in September 2011 which resulted in continuing approval and ISO certification through May 2013. In December 2010 / January 2011 we underwent an FDA audit; all findings from the audit were satisfactorily addressed." However, Defendants actively concealed the following:

(a) However, Defendants' site has been inspected 7 times since 06/25 - 07/09/2002. The most recent FDA audit occurred on 05/30 - 06/26/2013. The FDA has issued 4 Form 483 inspectional observations.

(b) However, Defendants actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483. *See Investigative Report attached hereto as Exhibit "C."*

(c) Most egregiously, Defendants was issued another Form 483 when it **"erroneously used non-conforming material."** Defendants actively concealed this and was issue another Form 483 for "failing to adequately document the situation." *See Investigative Report attached hereto as Exhibit "C."*

(d) However, Defendants' facility was also issued a violation as it **"no longer uses pre-sterile and post-sterile cages."** *See Notice of Violation attached hereto as Exhibit "D."*

(e) However, Defendants also was issued a violation when it **"failed to obtain a valid license...prior to manufacturing medical devices."** Defendants were manufacturing devices for three years without a license. *See Notice of Violation attached hereto as Exhibit "D."*

(f) Defendants failed to notice the FDA of their internal excel file containing **16,047 entries of complaints.**

(g) Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

124. The subsequent claims are based on Plaintiff's Essure and Defendants' failure to abide by FDA guidelines, Federal regulations and its own CPMA.

NEGLIGENT TRAINING – COUNT I

125. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

126. First, Defendants undertook an independent duty to train physicians on how to (1) properly use its device to place the micro-inserts and (2) in hysteroscopy which failed to abide by FDA training guidelines.

127. In fact, Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses-where Defendants observed physicians until Defendants believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure procedures."

128. As part of Defendants' training: Defendants had a duty to abide by the FDA training guidelines for the implanting physician on how to place Essure using its own delivery system and oversee this particular procedure. In addition, considering Defendants were providing the implanting physician with sophisticated hysteroscopic equipment, Defendants also had a duty to train the physician in hysteroscopy in a reasonably safe manner or at the very least ensure that the implanting physician was competent in hysteroscopy before providing them with the hysteroscopic equipment needed to place Essure. Defendants also had a duty to disclose adverse events to the physicians so that they in turn could properly advise their patients of the actual risks.

129. Defendants breached this duty by (1) failing to abide by the FDA training guidelines with Plaintiff's implanting physician, including providing training different from than

that of the "Physician Training Manual"; (2) failing to supervise the procedure; (3) failing to train Plaintiff's physician on how to use the hysteroscopic equipment provided by Defendants; and (4) failing to advise implanting physicians of the adverse events and non-conforming product so that Plaintiff could be properly advised of the known risks.

130. This breach caused Plaintiff's damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

131. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

132. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

133. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

134. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to her significant financial detriment and loss, and she may have to endure significant financial expenditures into the foreseeable future.

135. Plaintiff has suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiff demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory damages, punitive damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENT ENTRUSTMENT – COUNT II

136. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

137. Second, Defendants also provided and entrusted sophisticated hysteroscopic equipment to the implanting physician in order to sell its product.

138. The implanting physician was not competent to use such complicated devices, Defendants were aware of this, and provided the equipment anyway in order to sell its product.

139. Specifically, Defendants entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy, America, Inc. to (1) obtain specialized hysteroscopic equipment to then give to physicians and (2) to increase its sales force to promote Essure.

140. According to Defendants, these agreements allowed Defendants to "gain market presence…and expand … market opportunity by driving adoption among a group of physicians."

141. In regard to the entrustment of such specialized equipment, Defendants admitted: "We cannot be certain how successful these programs will be, **if at all.**" *See US SEC Form 10-Q: Quarterly Report Pursuant to Section 13 or 15(d)of the SEC Act of 1934.*

142. Defendants invested $5 million in capital expenditures related to purchases of hysteroscopy equipment to "hand out" to physicians. *SEC Form 10-K filed on 3/15/11 by Defendants.*

143. Moreover, Defendants stated: "We train and provide programs and all the elements that go into successful experience by the patient, including office staff training, equipment selection and other procedure room infrastructure, physician counseling skills, reimbursement and referral network building. *Defendants' Q4 2009 Earnings Call Transcript.*

144. Defendants had a duty not to provide sophisticated hysteroscopic equipment to the implanting physician who was not qualified to use such equipment. The implanting physician was not an expert hysteroscopist nor competent to use such equipment. Defendants were aware of this dangerous condition but provided the physician with the equipment in order to sell its product.

145. Defendants breached its duty by providing the implanting physician with hysteroscopic equipment in an effort to sell its product. Defendants also failed to reasonably investigate whether or not the implanting physician was competent to use such equipment.

146. This breach caused Plaintiff's damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

147. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

148. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

149. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

150. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to her significant financial detriment and loss, and she may have to endure significant financial expenditures into the foreseeable future.

151. Plaintiff has suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiff demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory damages, punitive damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

PHARMACOVIGILENCE- NEGLIGENT DISTRIBUTION / ADVERTISING / OVERPROMOTION / REPORTING – COUNT III

152. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

153. Defendants had a duty to **distribute, advertise, promote, and report adverse events** regarding Essure in a reasonably safe manner and to comply with the following Federal regulations and post-approval conditions contained in the CPMA:

(a) 21 C.F.R. 814, governing premarket approval of medical devices, a *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation **or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact,** even if the statement was not intended by the person making it to be misleading or to have any probative effect.

(b) 21 C.F.R. 814.80-A device **may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval** specified in the PMA approval order for the device.

(c) 21 C.F.R. 820.65- establish and **maintain procedures for identifying with a control number each unit, lot, or batch of finished devices** and where appropriate components. The procedures shall facilitate corrective action.

(d) 21 C.F.R. 803.1(a)- This part establishes **the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files.** If you are a manufacturer, you must also submit specified followup. **These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.**

(e) 21 C.F.R. 803.10- (a) If you are a device user facility, **you must submit reports** (described in subpart C of this part), **as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event :(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or,** if the manufacturer is unknown, submit reports to us.(2) Submit annual reports (described in 803.33) to us.(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or(ii) Submit reports of device-related malfunctions to the manufacturer.(2) [Reserved]**(c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or(ii) A reportable event for which we made a written request.(3)** Submit supplemental reports if you obtain information that you did not submit in an initial report.

(f) 21 C.F.R. 803.50(a)- (a) If you are a manufacturer, **you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information**, from any source, that reasonably suggests that a device that you market:(1) **May have caused or contributed to a death or serious injury**; or(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.(b) What information does FDA consider "reasonably known" to me?(1) You must submit all information required in this subpart E that is reasonably known to you. **We consider the following information to be reasonably known to you:(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;(ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.**(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.(3) **You are also responsible for conducting an investigation of each event and evaluating the cause of the event.** If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(g) 21 C.F.R. 803.53- **You must submit a 5-day report** to us, on Form 3500A or an electronic equivalent approved under 803.14, **no later than 5 work days after the day that you become aware that:(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.** You may become aware of the need for remedial action from any information, including any trend analysis; or(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(h) 21 C.F.R. 806.10- (a) **Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:(1) To reduce a risk to health posed by the device; or(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b).(b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days** of initiating such correction or

removal.(c) The manufacturer or importer shall include the following information in the report:(1) The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.(2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.(3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.(4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.(5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.(6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.(7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.(8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.(9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.(10) The date of manufacture or distribution and the device's expiration date or expected life.(11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.(12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.(13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.(d) If, after submitting a report under this part, a manufacturer or

importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available.(e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.(f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013]

(i) 21 C.F.R. 814.84-(a) **The holder of an approved PMA shall** comply with the requirements of part 803 **and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device.**(b) Unless FDA specifies otherwise, **any periodic report shall:(1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b).(2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:(i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.(ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.** If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted.(3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter.(4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

(j) 21 C.F.R. 820.65- **Each manufacturer of a device that is intended for surgical implant into the body** or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use

provided in the labeling can be reasonably expected to result in a significant injury to the user **shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.** Such identification shall be documented in the DHR.

(k) 21 C.F.R. 822-Post market surveillance- This part **implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices** that meet any of the following criteria:(a) Failure of the device would be reasonably likely to have serious adverse health consequences;(b) **The device is intended to be implanted in the human body for more than 1 year;**... The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

(l) 21 C.F.R. 820.100(a) 6 -7- Corrective and Preventive Action-(a) Each manufacturer **shall establish and maintain procedures for implementing corrective and preventive action.** The procedures **shall include requirements for:(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.** Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;(3) **Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions,** for management review.(b) All activities required under this section, and their results, shall be documented.

(m)21 C.F.R. 820.70(e)(h) (a) *General.* **Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any**

process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;(2) Monitoring and control of process parameters and component and device characteristics during production;(3) Compliance with specified reference standards or codes;(4) The approval of processes and process equipment; and(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.(b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40.**(e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.**(h) *Manufacturing material.* **Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.**

(n) 21 C.F.R. 820.90-(a) ***Control of nonconforming product.*** Each manufacturer **shall establish and maintain procedures to control product that does not conform to specified requirements.** The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. **The evaluation and any investigation shall be documented.**(b) *Nonconformity review and disposition.* (1) **Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented.** Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

(o) 21 C.F.R. 820.90-(a) Each manufacturer **shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination,** or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

(p) 21 C.F.R. 820.180- **All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available** for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(q) 21 C.F.R. 820.198-(a) **Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:(1) All complaints are processed in a uniform and timely manner;(2) Oral complaints are documented upon receipt; and(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.**(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.(c) **Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.**(d) **Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified.** In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:(1) Whether the device failed to meet specifications;(2) Whether the device was being used for treatment or diagnosis; and(3) The relationship, if any, of the device to the reported incident or adverse event.(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall

include:(1) The name of the device;(2) The date the complaint was received;(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;(4) The name, address, and phone number of the complainant;(5) The nature and details of the complaint;(6) The dates and results of the investigation;(7) Any corrective action taken; and(8) Any reply to the complainant.(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:(1) A location in the United States where the manufacturer's records are regularly kept; or(2) The location of the initial distributor.

(r) 21 C.F.R. 820.30 - Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, **shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.**

(s) 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a)- **A drug or device shall be deemed to be misbranded...If its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce...any device that is adulterated or misbranded.**

(t) 21 U.S.C. 351(a) (h)- **A drug or device shall deemed to be adulterated**...if it has been prepared, packed, or held under insanitary conditions whereby it **may have been contaminated with filth....or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice...if is...not in conformity with ...an applicable condition prescribed by an order.**

(u) 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- **In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular,** or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. **Restricted devices not carrying requisite accompanying statements in advertisements** and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes **in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer**, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand

name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

(v) FDA requirement in CPMA order- "Within **10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."**

(w) FDA requirement in CPMA order- **"Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests** that the device may have caused or contributed to a serious injury."

(x) FDA requirement in CPMA order- Report Due Dates- six month, one year, eighteenth month, and two year reports.

(y) FDA requirement in CPMA order- **A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.**

(z) FDA requirement in CPMA order- Warranties are truthful, accurate, and not misleading....Warranties are consistent with applicable Federal and State law.

154. Defendants breached these duties by violating the above mentioned Federal laws, and regulations and requirements of the CPMA including the following violations issued by the FDA (Plaintiff herein incorporates all violations attached as exhibits):

(a) Defendants **failed to timely provide the FDA with reports** after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteen month **and** two year reports. All reports failed to meet the respective deadlines. *Post approval Studies- ESS-305 Schedule attached as Exhibit "B."*

(b) Defendants failed to document successful placement of Essure concealing the failure rates.

(c) Defendants **failed to notice the FDA of several adverse reactions** and actively concealed the same. Defendant **failed to report 8 perforations** which

occurred as a result of Essure **and was cited for the same by the FDA** via Form 483.[8] *See Investigative Report attached as Exhibit "C."*

(d) Defendants **failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury** concealing the injuries. Again, Defendants **failed to report 8 perforations as adverse events which occurred as a result of Essure to the FDA as evidenced in** Form 483. *See Investigative Report attached as Exhibit "C."*

(e) As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

(f) Defendants' warranties were not consistent with applicable Federal and State law.

(g) Defendants failed to notice the FDA of their internal excel file containing **16,047 entries of complaints.** See Exhibit "E."

(h) Defendants **excluded the risk assessment for safety of loose coils in its Risk Management Plan** and stated the FDA found that Defendants had violated the FD&C Act. *Id.*

(i) erroneously **using non-conforming material** in the manufacturing of Essure; *See Investigative Report attached as Exhibit "C."*

(j) failing to use **pre-sterile and post-sterile cages;** *See Exhibit "D."*

(k) manufacturing Essure **at an unlicensed facility**; *See Exhibit "D."*

(l) manufacturing Essure for three years **without a license to do so.** *See Exhibit "D."*

(m)Not reporting ... complaints in **which their product migrated**; See *Exhibit "E."*

(n) **Not considering these complaints in their risk analysis for the design** of Essure; See *Exhibit "E."*

(o) **Failing to document CAPA activities** for a supplier corrective action; See *Exhibit "E."*

(p) On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 30 days of receiving or otherwise

[8] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FD&C Act rendering the device "adulterated."

becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011. **These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes**. Defendants were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

(q) Defendants **had notice of 168 perforations but only disclosed 22** to the FDA. *Id.*

(r) On January 6, 2011, **Defendants were cited for their risk analysis of Essure being incomplete.** Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

(s) On January 6, 2011, **Defendants were cited for not documenting Corrective and Preventive Action Activities.** Specifically, the FDA found that there **were failures in Defendants' Design**. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

(t) On July 7, 2003, Defendants were cited for not analyzing to identify **existing and potential causes of non-conforming** product and **other quality problems.** Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, **which is used to track the data.** (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went) See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

(u) On July 7, 2003, Defendants were cited for **not following procedures used to control products which did not confirm to specifications.** See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

(v) Defendants also breached this duty by requiring the implanting physician to purchase two (2) Essure "kits" per month **regardless of whether they used them or not** and by contracting with third parties from the hysteroscopic manufacturers to promote Essure who were not competent to perform the same.

(w) Defendants also breached this duty by failing to disclose to Plaintiff and her Implanting physician the fact that it **altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.**

155. This was an unreasonably dangerous and negligent distribution, advertising, promotion, and reporting plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff.

156. Plaintiff would never had Essure implanted in her had she known of the above.

157. This was also an unreasonably dangerous distribution scheme as it compelled the implanting physician to sell two (2) devices per month at the expense of Plaintiff's safety and well-being and also entailed representatives of third parties, who did not knowledge of Essure, to promote Essure.

158. Defendants also breached this duty by promoting Essure through representatives of hysteroscopic equipment companies who were not qualified to do the same.

159. This breach caused Plaintiff's damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

160. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

161. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

162. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

163. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to her significant financial detriment and loss, and she may have to endure significant financial expenditures into the foreseeable future.

164. Plaintiff has suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiff demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory damages, punitive damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENCE- RISK MANAGEMENT– COUNT IV

165. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

166. Defendant had a duty to have in place a reasonable risk management procedure to ensure, *inter alia*, (1) that adverse reports were being reported to the FDA; (2) that non-conforming product could be tracked appropriately (3) that adverse reports are considered in its risk analysis and to comply with the following Federal regulations and post-approval conditions contained in the CPMA:

> (a) 21 C.F.R. 814, governing premarket approval of medical devices, a *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation **or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material**